Section III (Remarks)

Summary of Amendments

The specification has been amended to correct a typographical error. On line 1 of paragraph [0056] of the specification, "gas pill 30" has been changed to read "gas pill 32" so as to refer to the correct element in Fig. 2.

Claim 41 has been amended to replace "a" with "at least one" on line 6, to replace "layer(s)" with "at least one layer" on line 9, and to incorporate the limitation of former claim 42 – namely, to recite that the film "provid[es] a seal that is degradable in exposure to physiological components in said gastric cavity." Support for the added limitation is provided in the original disclosure, for example, in paragraph number [0040].

In view of the amendment to claim 41, claim 42 has been canceled as redundant.

Claim 55 has been amended to insert an "a" in between "between" and "sealing film" on line 7, to insert "multilayer" between "said" and "film" on line 8, and – similar to claim 41 – to recite that the film "provid[es] a seal that is degradable in exposure to physiological components in said gastric cavity". Support for the added limitation is provided in the original disclosure, for example, in paragraph number [0040].

Elected claims 20-35, 41 and 43-56 are now pending as a result of the amendments to the claims, with claims 36-40 having been previously withdrawn.

No new matter within the meaning of 35 U.S.C. 132 has been added by the foregoing amendments.

Objection To Claim 55

In the February 23, 2006 Office Action, claim 55 was objected to as lacking the article "a" between the terms 'between' and 'sealing film'." Applicant has amended claim 55 to insert an "a" in between "between" and "sealing film" on line 7 and therefore respectfully requests that this objection be withdrawn.

Rejection Under 35 U.S.C. §112, Second Paragraph

In the February 23, 2006 Office Action, claims 41-56 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (Office Action, page 2). Specifically, the examiner stated:

> "Claim 41 is indefinite due to the use of "(s)" in "layer(s)". It is unclear to the examiner whether Applicants [sic – Shah is the only named inventor] mean to indicate this as a layer or layers. Applicants are required to have the parenthesis removed and write layer(s) clearly in its singular or plural form."

In response, claim 41 has been amended to replace "a" with "at least one" on line 6 and to replace "layer(s)" with "at least one layer" on line 9.

The examiner further stated:

> "Claim 55 is indefinite due to the limitation "said film" in line 8. It is unclear to the examiner which film Applicants are referring to. Clarification of "said film" is required."

In response, claim 55 has been amended to insert "multilayer" in between "said" and "film" in line 8. The term "said multilayer film" has antecedent basis in "a multilayer film" on line 6.

In view of these amendments, Applicant respectfully requests that the rejection of claims 41-56 under 35 U.S.C. §112 be withdrawn.

Rejection of Claims Under 35 U.S.C. §103, and Traversal Thereof

In the February 23, 2006 Office Action, claims 20-56 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,738,657 to Bryant et al. ("Bryant").

Such rejections are traversed in view of the foregoing amendments and the ensuing remarks.

1. Law Regarding Obviousness

Three requirements must be met for a *prima facie* case of obviousness. First the prior art reference(s) must teach all of the limitations of the claims. M.P.E.P. § 2143.03. Second, there

must be a motivation to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. In addition, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on Applicant's disclosure. M.P.E.P. § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)

2. Disclosure of Bryant

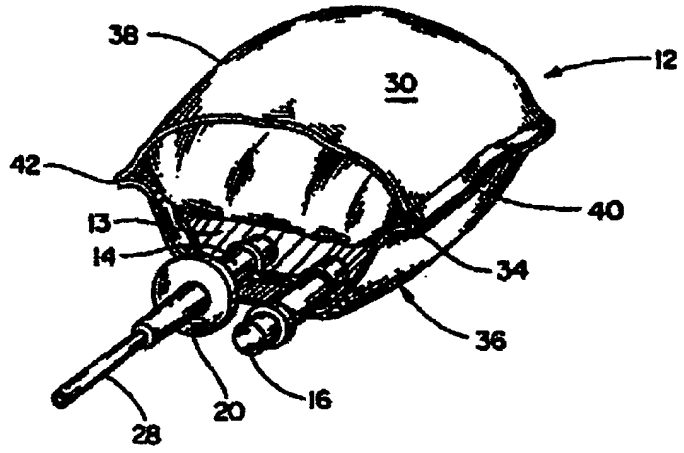
Bryant is directed to an ambulatory energized container system suitable for developing a of continuous pressure on, and flow of, a solution from a flexible bag of solution into a patient's indwelling vein access device so as to maintain a patient's vein open and ready to receive medication. Bryant, col. 1, lines 51-5. Bryant specifically describes a combination sleeve and bladder assembly, in which the sleeve accommodates insertion of an IV bag, and the bladder member is inflatable by gas-generating chemical means therein, to expand and apply continuous pressure against the IV bag, to provide positive pressure and continuous flow of IV fluid to a patient's vein. The gas-generating chemical means include reactants that are disposed within the bladder and normally segregated from one another (e.g., with a frangible seal) until deployed by a user. See, e.g., Bryant, col. 4, line 60 – col. 5 & line 2; col. 8, lines 8-21. In one disclosed embodiment a co-reactant within the bladder is contained in a capsule, which is manually breakable to expose the co-reactant to another chemical material for reaction therebetween.

A bladder according to Bryant is formed of flexible plastic material that can include at least two laminated layers of material having different material stiffness. Bryant describes a bladder formed of a laminate including a one mil sheet of polyvinylidene chloride, "laminated or coated to 20 mil of polyurethane, in either of two forms... the layer 56 of polyvinylidene chloride is laminated to the inner surface of a 20 mil layer 58 of polyurethane [and] in FIG. 11 the 1 mil layer 56 of polyvinylidene chloride is laminated and embedded between two 10 mil layers 58a of polyurethane." Bryant, col. 8, lines 44-50.

The sleeve portion of the sleeve and bladder assembly is stated to be "of a size to receive the 100 cc flexible bag 13 of saline solution" (Bryant, col. 7, lines 49-50) and Bryant refers to a "100 ml bladder portion" (Bryant, col. 10, line 52). The perspective view in FIG. 2 of Bryant (figure

reproduced below) shows the inflated bladder in a sleeve and bladder assembly in which the sleeve retains an IV bag 13 beneath the bladder 38.

FIG. 2



Bryant's sleeve and bladder assembly is intended for *ex situ* use – in other words, for use outside the human body. For example, referring to FIG. 8, the assembly includes "[a]n opening 48 for **attaching any number of known hangers ... so that the sleeve and bladder member 12 may be readily attached to a patient's clothing, be it a hospital gown or street wear.**" Bryant, col. 6, lines 43-47. See also Bryant col. 5, lines 8-11: "the sleeve and bladder member being attachable to the patient's wearing apparel, whether a hospital gown or street clothes.

3. Regarding Claims 20-35, Bryant Does Not Teach or Suggest A "Gastric Occlusive Device" With An "Effervescent Material ... Arranged For Contact With Introduced Liquid"

Independent Claim 20 recites, *inter alia*, a "**gastric occlusive device**" with an "effervescent material ... arranged for contact with **introduced liquid** reactive with the effervescent material." Neither of these limitations are taught or suggested by Bryant. As indicated previously, Bryant is directed to an *ex situ* ambulatory energized container system for pressurizing and delivering fluid from will flexible IV bag to a patient's indwelling vein access device. The bladder according to Bryant includes "normally segregated reactive **chemicals** disposed therein." See, e.g., Bryant, col. 4, line 60 – col. 5, line 2 & col. 8, lines 8-21. It is clear that these plural chemicals are **sealed and self-contained within the bladder** of the Bryant device. See Bryant, col. 8, lines 18-28, as reproduced below:

> A further gas-permeable, moisture-and-debris barrier means, in the form of a sealed, **folded packet 52** formed of a non-woven polypropylene fiber material, for example available commercially as Tyvek, **is sealed within the balloon 50. Disposed within the packet 52 are reactive chemicals such as sodium bicarbonate and citric acid, which chemicals are normally segregated for example by encasing the citric acid in a frangible ampoule 54. To provide the necessary volume of highly pressurized gas such as carbon dioxide, 41/4 grams of loose sodium bicarbonate are provided in the packet 52 and 21/2 cc.'s of 50% citric acid are provided in the ampoule 54, per 350 cc's of bladder volume. As the amount of citric acid controls the volume of gas generated, excess sodium bicarbonate may be present in the packet 52 and such excess is desirable.** When it is time to energize the bladder portion 38, the ampoule 54 may easily be broken by manually manipulating same through the flexible bladder portion 38, the balloon 50, and the packet 52.

Provision of all reactants within a bladder according to Bryant is perfectly workable with an *ex situ* fluid delivery device, but **inconsistent with an *in situ* gastric occlusive device to be inserted into a human patient**. Gastric occlusive devices claimed herein are preferably inserted through a patient's esophagus – i.e., without requiring surgical penetration of the abdominal wall. Accordingly, **minimizing uninflated volume of a gastric occlusive device is highly desirable to facilitate non-invasive device insertion while avoiding trauma to the patient's esophagus.** As a result, claim 20 recites "an effervescent material contained in said balloon, and arranged for contact with an **introduced liquid** reactive with the effervescent material." Introduction of such a liquid is described, for example, in paragraph [0038] of the disclosure, as reproduced in pertinent part below:

> "The balloon containing such effervescent material charge can be **injected, through the multilayer film** via a suitable self-sealing seal valve therein, **with a requisite amount of water or aqueous medium**. This injected water or aqueous medium then reacts with the effervescent material, to generate carbon dioxide as an inflation gas for the balloon."

Because a deflated gastric occlusive device **devoid of any liquid** can be inserted into the patient and **thereafter filled** (e.g., via a catheter or similar tube extending through the esophagus) *in situ* with liquid from an external liquid source, **the volume of the deflated gastric occlusive device is minimized** – thus desirably minimizing insertion-induced trauma to the patient's esophagus.

The **ability to introduce liquid from an external source into a gastric occlusive device after insertion into a patient's gastric cavity** has the further benefit of permitting the physician to control the ultimate inflation volume of the gastric occlusive device relative to the volume of an individual patient's gastric cavity. This contrasts sharply with the "one size fits all" approach of

the sealed system according to Bryant, in which the inflation volume of the bladder is established once the device is manufactured – *i.e.*, by the amount of reactive liquid (e.g., citric acid) present within the sealed packet 52 disposed within the bladder. See, e.g., Bryant, col. 8, lines 18-28.

For at least the reason that Bryant fails to teach or suggest a "gastric occlusive device" with an "effervescent material ... arranged for contact with introduced liquid reactive with the effervescent material," Bryant fails to teach all of the limitations of claim 20 as would be required by MPEP § 2143.03 to support a *prima facie* case of obviousness. Likewise, since claims 21-35 depend from, and therefore include all of the limitations of, claim 20, no *prima facie* case of obviousness has been established as to claims 21-35 either.

4. Regarding Claims 41 and 43-56, Bryant Does Not Teach or Suggest A "Seal That Is Degradable In Exposure To Physiological Components In [A] Gastric Cavity"

Independent claims 41 and 55 recite, *inter alia*, that the gastric occlusive balloon "including a film providing a seal that is degradable in exposure to physiological components in said gastric cavity" such that the resulting film is "adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said subject and to deflate after said period of time by egress of said inflation medium through the film." **Nothing in Bryant teaches or remotely suggests use of the disclosed ambulatory energized container system as a gastric occlusive balloon, much less teaching or suggesting a seal that is degradable in exposure to physiological components in a gastric cavity.** To the contrary, Bryant teaches that the "bladder can be formed of a **relatively tough plastic** such as polyurethane, polyvinylidene chloride, fabric reinforced polyurethane, shore 90A durometer material and the like and combinations thereof" (Bryant, col. 4, lines 47-50) and that the "combination sleeve and bladder member 12 [is] formed of a relatively rugged and tough plastic film material" (Bryant, col. 5, lines 45-49).

For at least the reason that Bryant fails to teach or suggest a "seal that is degradable in exposure to physiological components in [a] gastric cavity," Bryant fails to teach all of the limitations of independent claims 41 and 55 as would be required by MPEP § 2143.03 to support a *prima facie* case of obviousness. Likewise, since claims 43-54 and 56 depend from, and therefore include all of the limitations of, claims 41 and 55, respectively, no *prima facie* case of obviousness has been established as to claims 43-54 and 56 either.

5. As To All Of Claims 20-35, 41 and 43-56, Bryant Fails To Teach or Suggest A Generally Spherical Balloon Having An Inflated Diameter From 3 to 5 Inches And A Multilayer Film Thickness of Up To 10 Mils

Each of claims 20-41 and 43-56 recite the following limitations:

> said balloon in an inflated state has a diameter in a range of from 3 to 5 inches, said balloon is generally spherical in shape, and said multilayer film has a thickness of up to 10 mils.

Regarding the "thickness of up to 10 mils" limitation, Bryant teaches a barrier means that takes the form of one of two arrangements. The first form is a 1 mil sheet laminated to the inner surface of a 20 mil layer. The second form is a 1 mil sheet embedded in between two 10 mil layers. **In either form, the result is a 21 mil layer barrier means.** Contrary to the examiner's assertion that the reference "teaches the polyvinylidene chloride layer to be 1 mil and the polyurethane layer to be 10 mil or 20 mil" (Office Action, section 10, lines 12-14), Bryant does **not** teach a polyurethane layer being either 20 mil **or** 10 mil. Rather, Bryant teaches a polyurethane layer of 20 mil, or **two polyurethane layers of 10 mils each.**

Furthermore, Bryant does not provide any motivation for providing a bladder of less than 20 mils thick. To the contrary, Bryant recites the use of "tough plastic" at col. 4, lines 46-50: "[t]he bladder can be formed of a relatively tough plastic such as polyurethane, polyvinylidene chloride, fabric reinforced polyurethane, shore 90A durometer material and the like and combinations thereof." Bryant's need for a tough material is apparent from the use of a chemical–containing internal ampoule or capsule intended to be broken by a user, since after the ampoule is broken, the bladder, and layers laminated to it, must be able to contain "all fragments of the ampoule 54 which could have sharp edges." (Bryant, col. 8, lines 35-36) Given the danger of puncture inherent to a device according to Bryant, the reference ***teaches away*** **from the use of thinner laminates** having an aggregate thickness of less than Bryant's disclosed **21 mil thickness value.**

Regarding the spherical shape limitation, it is apparent that the inflated bladder of Bryant is not "generally spherical" in character as required by all of applicant's claims, but rather has a flattened rectangular pillow shape (see Fig. 2 reproduced hereinabove), consistent with the fact that Bryant's device is an *ex vivo* pressure applicator for fluid dispensing, and not a device to be employed *in vivo* to combat obesity as is applicant's invention. Specifically, Bryant discloses:

> "the combination sleeve and bladder member 12 is formed by **three generally rectangular sheets** 30, 32, and 34 of plastic, such as polyurethane or polyurethane-coated fabric, which

> overlie one another and are sealed together, as by welding" (col. 6, lines 11-15) ... whereby sheets 30 and 32 **define the four-sided sealed bladder portion** 38 with sheet 30 serving as the outer side wall thereof and sheet 32 serving as the inner side wall thereof" (col. 6, lines 29-32) (emphasis added).

Regarding the diameter (size) limitation, it is unclear that a "diameter" as a unit of measure has any applicability to the pillow-shaped apparatus of Bryant. Bryant fails to use the term diameter to characterize bladders disclosed therein. For the sake of argument, however, even if it were assumed that the pillow-shape of Bryant were spherical, Brant refers to "a 100 ml bladder portion" (col. 10, line 52). Noting that:

- 100 ml (milliliters) is equivalent to 100 cc (cubic centimeters);
- 100 cc is equivalent to 6.1 cubic inches (in^3);
- the volume of a sphere is calculated as $4/3\ \pi\ r^3$ (with the radius r being half the diameter); and
- a sphere having a diameter of 3 inches to 5 inches has a volume between 14.1 in^3 and 65 in^3 (cubic inches),

the spherical balloon of the present claims has a bladder volume that is between 2.3 and 10.7 times greater than the bladder disclosed by Bryant. Such a large diameter / volume is consistent with the application of the presently claimed balloon devices as gastric occlusive devices. The **examiner points to no teaching or suggestion whatsoever in Bryant that an "ambulatory energized container system" according to Bryant should be modified to match the limitations of the present claims 21-41 and be put to use as a gastric occlusive device.** To establish a prima facie case of obviousness, any teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on Applicant's disclosure. M.P.E.P. § 2143.

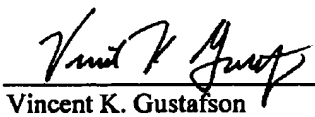
Thus, for at least the reasons that Bryant fails to teach or suggest all of the limitations of claims 20-41 and 43-56 (e.g., a generally spherical balloon having an inflated diameter from 3 to 5 inches and a multilayer film thickness of up to 10 mils), as would be required by MPEP § 2143.03, and no motivation to modify Bryant to yield the presently claimed invention has been identified as required by MPEP § 2143 (see also *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)),

no *prima facie* case of obviousness has been established. Withdrawal of the rejections under § 103(a) is respectfully requested.

CONCLUSION

Claims 20-35, 41, and 43-56 as provided herein are now in form and condition for allowance. It therefore is respectfully requested that such claims now be allowed. Applicant further renews its request that non-elected claims 36-40 now be rejoined with such claims 20-35 and 41-56 under the applicable rejoinder provisions of MPEP §821.04. If any issues remain outstanding, incident to the formal allowance of the application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same, in order that this application may be allowed and passed to issue at an early date.

Respectfully submitted,



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